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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/514,426	02/28/2000	Henning Rud Anderson	14635-007890US	8798

7590 04/02/2002

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EXAMINER

WILLSE, DAVID H

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 04/02/2002

#11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/514,426	ANDERSEN ET AL.
	Examiner	Art Unit
	Dave Willse	3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 14 January 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 9-12 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-8 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____ .
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>10</u> | 6) <input type="checkbox"/> Other: _____ |

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The Official Draftsperson has approved the Formal Drawings received on January 14, 2002.

The amended abstract of the disclosure is objected to because of the inclusion of legal phraseology (e.g., "means . . ." on line 5 and others). Correction is required (MPEP § 608.01(b)).

Claims 5-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 5, line 2 lacks proper syntax; on line 5, "that" should be replaced by -- than--.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4 and 8 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Ersek, US 3,657,744. Particular attention is directed to Figure 8; column 2, lines 38-43 and 56-59; and column 4, lines 25-31. Regarding claim 3: Figures 3 and 4; column 3, lines 41-55. Regarding claim 4: column 4, lines 25-33.

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Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ersek, US 3,657,744. The loop or serpentine pattern was well known in the stent art and would have been an obvious variant in view of its advantages over the mesh structure of Ersek. To provide loops of greater height would have been obvious from purpose of the openings 25 or the struts 28 illustrated in Ersek. Regarding claim 7, three or more rings would have been obvious in order to increase the length and the axial flexibility of the stent so as to support aortic segments (column 4, lines 27-28) and the like, with further motivation having been provided at column 4, line 5.

Response to Applicant's Remarks

The Applicant argues that “[t]he fixation sleeves disclosed in Ersek could not be compressed to the degree necessary to fit within a catheter” (Paper No. 8: page 6, lines 5-6). It is not seen how the term “catheterization” *necessitates* the insertion of the implant *into* the catheter: for example, a stent may be mounted “*around* the expansion arrangement of the catheter” (Applicant’s specification: page 3, lines 25-27; Figure 3; emphasis added). Moreover, the Ersek “sleeve may easily be expanded by about 50 percent beyond its original diameter” (column 3, lines 15-17) and “expands so that a snug fit is assured regardless of the size, shape or consistency of the tissue wall at the implantation situs” (column 1, lines 64-66). Thus, the Ersek sleeve is certainly *capable* of fitting *within* a catheter tube, whether or not such was the intent.

The Applicant further contends that “[t]he mesh design of the fixation sleeves of Ersek offer very little compression” (Paper No. 8: page 6, line 7). The Ersek sleeve is made of a deformable material (column 2, line 56) and is certainly capable of being compressed onto the expansion means 35-37 (Figures 1 and 6) for temporary securement therewith. The Applicant’s

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specification plainly indicates that mesh or grate designs can, in fact, be used (page 3, lines 23-24; page 10, lines 19-22).

Regarding claim 3, the ring portions or sections have edges defined by apices of the diamond shapes; the term "side" (claim 3, line 2) is deemed to be quite broad in scope.

Regarding claim 5, the examiner has already cited a patent (US 4,994,077: column 3, lines 53-58) which shows that the looped design was well known in the art at the time of the present invention. There would have been motivation to consider other stent designs because the Ersek invention is directed to "*instant and positive* fixation of heart valves" (column 1, lines 54-56; emphasis added) so that "in many instances use of the heart-lung machine is not required" (column 1, lines 63-64). Furthermore, it is the examiner's opinion that loops of different heights would have been obvious in order to define openings for matching with the coronary ostia. It is also noted that the Applicant's disclosure appears to assign little, if any, criticality in the design set forth in present claims 5-7, as seen from page 10, lines 13-24, of the specification.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse, whose telephone number is (703) 308-2903 and who is generally available Monday through Thursday during most of each day. The supervisor, Corrine McDermott, can be reached at (703) 308-2111. The receptionist's phone number is (703) 308-0858, and the main FAX numbers are (703) 305-3591, 3590.

dhw: D. Willse

April 1, 2002


DAVE WILLSE
PRIMARY EXAMINER
ART UNIT 3738